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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,782	01/28/2004	Steve A. Yon	135001	7291

7590

06/28/2005

Mayer Fortkort & Williams
251 North Avenue West
Westfield, NJ 07090

EXAMINER

GIBSON, ROY DEAN

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 06/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/767,782

Applicant(s)

YON ET AL.

Examiner

Roy D. Gibson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 22-30 is/are allowed.
- 6) ☒ Claim(s) 1-21, 31-44, 47, 49, 51-54, 57-60 and 63 is/are rejected.
- 7) ☒ Claim(s) 45, 46, 48, 50, 55, 56, 61 and 62 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/2/04 & 1/21/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Double Patenting

Claims 2, 7-12, 16-21, 31-39 and 43 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 7-12, 16-21, 31-39 and 42 of copending Application No. 10/219,814. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-5, 44, 47 and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Machold et al. (6,695,874).

As to claims 1 and 3-5, Machold et al. discloses a method of controlling the administration of a thermal therapy, comprising:

inserting a catheter having a heat transfer element positioned at a distal tip of the catheter into a blood vessel of a patient the catheter having a supply lumen for supplying a working fluid to the heat transfer element and a return lumen for returning a working fluid from the heat transfer element:

circulating a working fluid through the catheter and the heat transfer element the working fluid having a temperature different from the patient temperature;

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receiving a signal from a temperature sensor mounted in one of the supply lumen or the return lumen;

determining a control temperature based on the signal;

using the control temperature to control the temperature of the working fluids

wherein the temperature sensor is selected from the group consisting of

thermistors, thermocouples and combinations thereof;

further wherein the temperature sensor is two thermistors; further comprising

receiving a safety monitor signal from one of the two thermistors; and

further comprising causing the working fluid to stop circulating if a value

of control temperature measured by the safety monitor signal falls outside a

predetermined range (col. 1, lines 18-57, col. 4, lines 52-62, col. 9, line 39-col. 11, line 25 and col. 41, lines 1-14).

As to claims 44, 47, 49, 60 and 63, Machold et al. disclose a heat transfer catheter made of a polymer and otherwise essentially as claimed and wherein the temperature sensor is a thermistor or thermocouple, and further disclose a guidewire (78) and lumen disposed within the catheter and coupled to the supply lumen, the supply lumen terminating proximal of the guidewire lumen (col. 9, lines 21-67).

Claim 42 is rejected under 35 U.S.C. 102(e) as anticipated by Dae (6,231,594).

Dae discloses a computer program for causing a machine to receive a signal from a temperature sensor, inherently mounted in either the supply or return lumen in which working fluid is flowing;

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determine a control temperature based on the signal; and
use the control temperature to control the temperature of the working fluid(col. 18, lines 18-64).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13-15, 41, 52, 53 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Machold et al. Although Machold fails to disclose the temperature sensor is disposed in a polymer (polyamide) or metal tube within the supply or return lumen, the examiner maintains these limitations are merely design choices and that it would have been an obvious matter of design choice to a person of ordinary skill in the art to provide the sensor and its signal lines as claimed because Applicant has not disclosed that such a location and material provides an advantage, is used for a particular purpose, or solves a stated problem.

Claims 6 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Machold et al. in view of Dae (6,231,594).

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As to claim 6, Machold et al. discloses inducing hypothermia which is generally well known in the art to be from 32-36 degrees C, which is also taught by Dae in col. 6, lines 15-30.

As to claim 40, Machold et al. lacks the specific disclosure of administering an anti-shivering agent to the patient. But, Dae discloses a method of inducing hypothermia with a similar intravascular catheter and the further step of administering an anti-shivering agent to the patient (col. 5, line 40-col. 7, line 26). Therefore, at the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the method of Machold et al., as taught by Dae, to administer an anti-shivering agent to the patient to reduce the degree of shivering by the patient or its onset entirely.

Allowable Subject Matter

Claims 22-30 are allowed.

Claims 45, 46, 48, 50, 51, 61 and 62 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

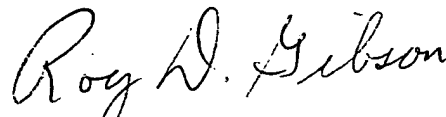
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy D. Gibson whose telephone number is 571-272-4767. The examiner can normally be reached on M-F, 7:30 am-4:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Roy D. Gibson
Primary Examiner
Art Unit 3739

June 10, 2005